BEFORE THE MINNESOTA
BOARD OF PHARMACY

In the Matter of the Proposed Rule Amendments Relating to definitions, license categories, pharmacy satellites, patient access to pharmacists, closing a pharmacy, required reference books and equipment, applications for licensure, reciprocal licensure, drug manufacturer or wholesaler licensure, pharmaceutical waste, vending machines, return of drugs and devices, prescription numbers, electronic prescriptions, compounding and dispensing, transfer of prescriptions between pharmacies, prepackaging and labeling, pharmacy compounding practices, beyond-use dates, prescription labeling, labeling of out-patient intravenous admixture drugs, electronic data processing, Schedule III and V controlled substances, registration of controlled substance researchers, controlled substance samples, prescription order communication, hospital pharmacist-in-charge, patient care, pharmaceutical service policies, policy and procedures manuals, physical requirements, service and filing of papers, variances, registration of medical gas retailers, and continuing pharmaceutical education.

STATEMENT OF NEED AND REASONABLENESS

I. INTRODUCTION

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. Sections 14.22 through 14.28 and Minn. Rules 1400.2000 through 1400.2570, hereby affirmatively presents the need for and facts establishing the reasonableness of the above-captioned proposed amendments to portions of the Board's rules relating to pharmacy practice.

II. ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make a request for an alternative format, contact Cody Wiberg at the Minnesota Board of Pharmacy, 2829 University Avenue SE, Suite 530, Minneapolis, Minnesota 55414-3251, phone (651) 201-2825, or fax (651) 201-2837. TTY users may call (800) 627-3529.

III. STATUTORY AUTHORITY

The statutory authority for these proposed rule changes is contained in Minn. Stat. Sections 151.06, which provides the Board with general rule-making authority relating to the practice of pharmacy, and 152.02, subd. 7, which specifically provides the Board with authority to reschedule controlled substances.

IV. NEED FOR THE RULES

The professional practice of pharmacy continuously evolves, requiring the Board to periodically revise its existing rules to address changes in practice. In addition, actions of the United States Congress, the Food and Drug Administration, the Drug Enforcement Administration and other federal agencies often require changes in the Minnesota Rules for pharmacy.

The changes to the Board's rules proposed in this rules package address various issues.

6800.0100 DEFINITIONS

Beyond-use date and expiration date. The United States Pharmacopoeia (USP) defines "beyond-use date" as the date after which a drug should not be used. The expiration date printed on a drug package is set by the drug manufacturer. The manufacturer certifies that the product will maintain at least 90% of its original potency until the expiration date. The certification requires the product to be stored according to label directions with the original packaging intact and unopened.

Drugs dispensed in the original packaging retain the manufacturer's expiration date, but when a pharmacist compounds a drug product or repackages commercially available drugs into consumer containers, the manufacturer's expiration date should no longer be used. Instead, the pharmacist is supposed to assign a beyond-use date.

Definitions of "beyond-use date" and "expiration date" need to be added to Minnesota Rules 6800.0100 because, if this rules package is adopted in its entirety, both terms will be used. In the past, only the term "expiration date" was used. Defining both terms in rule will minimize the chance of confusion on the part of individuals who are trying to follow the rules.

Central service pharmacy. In recent years, some pharmacies have started using what are commonly referred to as central fill or central service pharmacies (CSP). A CSP performs tasks such as drug utilization review (DUR) and prescription filling functions such as packaging, labeling, and billing. The CSP passes on information concerning the DUR and/or delivers filled prescriptions to another pharmacy, rather than directly to a patient. The other pharmacy actually dispenses the drug to and counsels the patient. For example, a chain of pharmacies may establish one pharmacy to process most requests for refills of maintenance medications.

A central service pharmacy usually operates in a manner that is distinct from the types of pharmacies currently licensed by the Board. Therefore, it is necessary to create a new central service license category. Consequently, "central service pharmacy" needs to be defined in rule.

Community Satellite and Hospital Satellite. In the past satellite pharmacies were found in the hospital setting. The satellite was dependent on the main hospital pharmacy for administrative control, staffing and drug procurement. Recently, pharmacies have opened that operate as satellites of community pharmacies. It is necessary to distinguish between community and hospital satellites since community satellites are not necessarily located within the same facility, as are hospital satellites. Community satellites, like any pharmacy, must be staffed by a pharmacist and must adhere to the previously established requirements for establishing a satellite that are found in Minnesota Rules 6800.0800, subp. 3.

The definition of a hospital satellite has not been changed.

Long-term care pharmacy. The definition of long-term care pharmacy is being expanded to include pharmacies that provide services to assisted living facilities. Such facilities are increasing in number and the services provided to them are similar to the services that pharmacies provide to licensed nursing homes, boarding care homes and supervised living facilities. That being the case, pharmacies servicing assisted-living facilities need to follow the rules for providing services to long-term care facilities.

6800.0350 LICENSE CATEGORIES

As mentioned above, some pharmacies have started using what are commonly referred to as central fill or central service pharmacies (CSP). A CSP performs tasks such as drug utilization review (DUR) and prescription filling functions such as packaging, labeling, and billing. The CSP passes on information concerning the DUR and/or delivers filled prescriptions to another pharmacy, rather than directly to a patient. The other pharmacy actually dispenses the drug to and counsels the patient. For example, a chain of pharmacies may establish one pharmacy to process most requests for refills of maintenance medications.

A central service pharmacy usually operates in a manner that is distinct from the types of pharmacies currently licensed by the Board. Therefore, it is necessary to create a new central service license category.

6800.0800 LOCATION, DIMENSION, OR SECURITY CHANGES

Subp. 3 Establishment of a satellite. This subpart is being changed so that a pharmacy seeking to establish a satellite must provide the Board with operational policies and procedures for the satellite. The Board is receiving requests for approvals of different types of satellite pharmacies. In order to properly evaluate such requests, it is necessary to review both the plans for the satellite and also the satellite policies and procedures.

6800.0910 PATIENT ACCESS TO PHARMACIST

Approximately 16 years ago the United States Congress passed the Omnibus Budget Reconciliation Act of 1990 (OBRA-90). Incorporated within the various sections of OBRA-90 was a provision requiring each state to develop laws or rules requiring pharmacists to provide prospective drug-utilization review and to provide patient counseling services to all Medicaid patients, in order to maximize the effectiveness of drug therapy for these patients and, as a result, to decrease the overall healthcare costs to the federal government.

In Minnesota, the Legislature amended Minn. Stat. 151.06, directing the Board of Pharmacy to mandate the OBRA-90 DUR and patient counseling requirements through its rulemaking process. In 1992 and 1993, the Board worked to promulgate rules necessary to implement the requirements of OBRA-90. As was done in most other states, the Board of Pharmacy proposed to expand the DUR and patient counseling requirements of OBRA-90 to all patients in Minnesota, rather than limiting the requirement for these services only to Medicaid patients. The Board's proposal met with significant opposition at the hearing held on the proposed rules and the DUR and patient counseling requirements of OBRA-90 were, subsequently, limited to Medicaid patients only. Minnesota, thus, became one of only ten states that did not expand the DUR and patient counseling requirements of OBRA-90 to all patients within the state.

By 2001, additional studies had taken place that validated the hypothesis that drug use review and patient counseling play a valuable role in maximizing the effectiveness of drug therapy and lowering overall healthcare costs. In addition, support for the concept of pharmacist involvement in drug therapy management had grown among members of the profession. There also appeared to be general support within the profession in Minnesota for the expansion of the DUR and patient counseling requirements of OBRA-90 to all patients within the state. Therefore, the Board proposed changes to Minn. Rule 6800.0910 and 6800.3110 to eliminate the double standard of pharmaceutical care that had been in existence in Minnesota for the previous ten years. The rule change was adopted, and it was hoped that all patients in Minnesota would receive DUR and patient counseling services from their pharmacist.

DUR and patient counseling services are particularly important when prescriptions for drugs that the patient has never previously taken are dispensed. While the Board has noticed some improvement on the part of pharmacists in providing DUR and counseling services to patients receiving new prescriptions, there is still room for further improvement. The current rule allows a pharmacist's designee, often a clerk, to make the offer of counseling on the pharmacist's behalf. In the judgment of the Board, more patients would be counseled if the pharmacist was required to personally initiate the counseling of a patient for whom a new prescription was being dispensed, rather than having a designee make an offer to counsel.

In regards to prescriptions that were previously dispensed, commonly referred to as refills, the proposed language requires that a pharmacist must counsel a patient if, based

on his or her professional judgment, it is necessary to do so. In order to exercise professional judgment, a pharmacist would need to perform the tasks mentioned in the language that is being proposed for deletion. Consequently, there is no need to retain the language in the rule.

6800.1010 CLOSING A PHARMACY

The Board is proposing to delete language that requires a closing pharmacy to notify the United States Drug Enforcement Administration (DEA) of the closing and to return the pharmacy's DEA Certificate and order forms to the DEA. The DEA already requires a pharmacy that closes to notify the DEA of the closure and to return the certificate and order forms. Therefore, it is more appropriate for the DEA to enforce these requirements, since it is the agency that issues the certificate and order forms.

6800.1050 REQUIRED REFERENCES BOOKS AND MINIMUM EQUIPMENT FOR PHARMACIES

As might be expected, references books concerning the practice of pharmacy, prescription drugs and toxicology change in terms of their content, format and availability. Since this rule was last amended, some reference books have gone out of print and new ones have been written. Also, many references are now available in a variety of electronic formats. Consequently, it is necessary to update the list of suggested references. The Board also wants to clarify that most references can be available in an electronic format, rather than as a printed, hard copy book.

The Board receives questions on almost a daily basis concerning controlled substances, indicating that a significant number of pharmacists are not fully aware of the applicable Drug Enforcement Agency regulations (21CFR Part 1300 to 1399). Therefore, each pharmacy should have a current copy of the DEA regulations on hand to minimize the chance that pharmacists will fill prescriptions for controlled substances in violation of federal law.

Certain specialty pharmacies serve unique populations and those pharmacies should have at least one current reference appropriate to the patient population served. For example, pharmacies that primarily serve patients in long-term care facilities should have a reference concerning geriatric pharmacotherapy, since many of the residents of those facilities are elderly. This will help ensure that drug therapy for the patients served will be safe and effective.

The United States Pharmacopoeia (USP) has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). Included in these chapters are requirements for the type of equipment that must be used. Consequently, the Board believes that all pharmacies should have equipment that is in compliance with USP 795 and that pharmacies that engage in sterile compounding should have equipment that is in compliance with USP 797 and a copy of USP 797.

In order to ensure that drugs that require refrigeration are stored at the proper temperature, the Board has long required that pharmacies have a refrigerator with a thermometer. However, the Board is aware of pharmacies that do not routinely monitor the temperature in the refrigerator. The Board believes that pharmacies should monitor temperatures in the drug refrigerator on a daily basis. That will help ensure that drugs that are stored at a temperature outside of the manufacturer's recommend range will not be dispensed to patients.

6800.1250 APPLICATIONS FOR LICENSURE

Until January of 2005, the Board required applicants for licensure by examination to complete a practical examination, which was offered at certain times during the year. An application, along with supporting documentation and the appropriate fee, was due into the Board offices 45 days prior to the examination. At its October 2004 meeting, the Board voted to discontinue the practical examination as part of the overall examination process for new licensees.

At that meeting, the Board reviewed the blueprint for the new National Association of Boards of Pharmacy (NABP) developed North American Pharmacist Licensure Examination (NAPLEX), and determined that the competencies being tested for in the Board's practical examination would be adequately covered. Unlike the Board's practical examination, the NAPLEX can be taken at any time, provided an applicant has met all of the other requirements for licensure. Since there is no longer a set time at which an examination takes place, the 45-day requirement is no longer applicable. Instead, the Board proposes that the application, supporting documentation and fee be received in the Board offices before approval to sit for the examinations will be granted.

Currently, there is no time period during which an applicant must complete all of the steps necessary for licensure. In some cases, applicants have waited for over two years before seeking permission to sit for the required examinations. The longer the delay in completing the application process, the more likely it is that some change in circumstance will occur that would be of concern to the Board. Therefore, it would be beneficial to require that an applicant, who has not completed all of the steps necessary for licensure within 18 months, reapply so that the Board can review the applicant's qualifications to be licensed.

Several years ago, the Board of Pharmacy formally adopted a rule change of M.R. 6800.1150 that increased the pharmacist licensure fee from $95 to $105. Unfortunately, Subpart 1a of this rule was not amended to also reflect that increase. Therefore, the proposed change of this subpart is merely a technical correction.

6800.1300 RECIPROCITY

As with applicants for licensure by examination, the Board no longer requires applicants for licensure by reciprocity to pass a practical examination. (See discussion about Part 6800.1250 above). As a result, there is a need to update this rule to reflect the

fact that applications for licensure by reciprocity are now considered at any time during the year, not just in January and June. Although the practical examination is no longer offered, it is the judgment of the Board that it still necessary for applicants who have not engaged in practice as a licensed pharmacist to demonstrate continued competency. Therefore, the Board is proposing that such applicants be required to take and pass the NAPLEX examination.

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE

Minnesota Rules 6800.9921 concerns the registration of certain persons or establishments that sell or distribute legend medical gases in Minnesota. It reads, in part: "Employees of an establishment need not register if the establishment is registered or has applied for registration'. This conflicts with Part 6800.1400, so this proposed rule change clarifies that such persons do not have be annually licensed by the Board under Minnesota Rules 6800.1400.

6800.1500 CONTINUING EDUCATION

An organization that accredits continuing education programs and providers has changed its name from the American Council on Pharmaceutical Education to the Accreditation Council for Pharmacy Education. Consequently, one part of this proposed rule change alters the references to that organization to reflect the name change.

M.S. § 326.56, subd. 2 states, in part, that individuals who are called to active, overseas military duty are:

> "exempted from the payment of all renewal fees and from the filing of any application for renewal, which but for this section would have been required as a condition of the renewal of the license or certificate, during the time the person has been in such armed forces or in such employment, and from any penalties for nonpayment or late payment, and is hereby exempted from further payment of such renewal fees and from the making of any application for renewal during the period the person shall remain in such armed forces or is engaged in such employment, and for a further period of six months from discharge from the armed forces, if a member thereof, or from the date of return within the boundaries of the United States if engaged in the employment herein before referred to".

This statute specifically mentions renewal fees, penalties for nonpayment of renewal fees and the process of making an application. It does not specifically mention other licensing requirements such as completion of continuing education. However, in the judgment of the Board it is probable that the legislature intended that licensing agencies make reasonable accommodations for individuals called to active duty. Therefore, the Board proposes to exempt pharmacists who are called to active, overseas duty from the continuing education requirements of Minnesota Rules 6800.1500.

The Board allows pharmacists to file an application for an extension of time, not to

exceed one year, to comply with the continuing education requirements specified in this rule. Processing, reviewing and following up on such applications require time and effort on the part of Board members and staff. Therefore, it is reasonable to recover the costs associated with processing and following up on these applications by requiring payment of a $100 fee.

6800.2350 PHARMACEUTICAL WASTE

Many prescription drugs are considered by either federal or state agencies to be hazardous waste when they are disposed of. For example, many of the drugs used to treat cancers are highly toxic. In addition, many of the chemicals used by pharmacists during the extemporaneous compounding of drug products are toxic, flammable or corrosive. If improperly disposed of, these prescription drugs and chemicals pose a risk to the public. Board staff recently discussed this issue with staff from the Minnesota Pollution Control Agency (MPCA), which regulates the disposal of hazardous pharmaceutical wastes. The MPCA has started to actively enforce its rules concerning disposal by healthcare facilities of hazardous wastes.

Therefore, in the judgment of the Board it is necessary to require that disposal of hazardous pharmaceutical waste be in compliance with Minnesota Hazardous Waste Rules, Chapter 7045.

6800.2600 VENDING MACHINES

The use of automatic medication management systems to distribute prescription drugs has steadily increased over the past several years. While these systems can lead to increased efficiencies and reduce certain types of errors, they can also cause other types of errors. Board of Pharmacy Surveyors, during inspections, have noted deficiencies in the policies and procedures of some facilities using these systems. If Board staff can review policies and procedures prior to the Board's authorization of the use of an automatic medication management system, suggestions can be made that will minimize the chance of errors.

6800.2700 RETURN OF DRUGS AND DEVICES

In general, pharmacists and pharmacies are prohibited from accepting from patients or their agents any drugs or prescribed medications and then reuse, reissue, or resell those products. The rationale is that, once a drug or prescribed medication leaves the control of the pharmacy, there is no way for a pharmacist to be certain that the product has been handled and stored properly. Also, in some cases, tampering with a drug or prescribed medication might not be readily evident. In short, dispensing a returned drug to another patient might put that second patient at risk.

Currently there are two exceptions to this general rule. In a hospital with a licensed pharmacy, drugs, devices and other items dispensed for hospital inpatient use can be returned to the pharmacy for disposition by a pharmacist in accordance with good

professional practice Drugs from nursing homes may also be returned to the dispensing pharmacy if certain conditions are met. For both of these exceptions, previous Boards made the determination that the pharmacist accepting the return drugs could be reasonably certain that they had been handled and stored properly and that they had not been tampered with. Note that for both exceptions, other licensed health professionals would either have control of the dispensed drugs or be able to monitor them 24 hours per day, seven days per week. (Specifically, licensed nurses working on the nursing units of hospitals or in licensed nursing facilities).

The Board is proposing amendments to this rule to further ensure that returned drugs are safe to reissue to other patients. An amendment to subpart 1 clarifies that, in a hospital setting, drugs can be returned for reuse or disposal only if they were dispensed for hospital inpatient use and they have not left the span of control of the pharmacy. Minnesota Rules 6800.7400, Subp. 5 defines the span of control to be all areas of the hospital where drugs are stored. Such areas currently must be inspected by a pharmacist no less than every two months. If this entire rule package is adopted, such areas will have to be inspected at least monthly. Thus, if this rule change is adopted, drugs not stored in areas regularly inspected by a pharmacist could not be returned to the pharmacy for reuse.

The Board is also proposing to amend Subpart 1 by replacing the somewhat nebulous phrase "disposition by a pharmacist" with the phrase "reuse or disposal". Using the word "disposal" emphasizes that, if the drug can't be reused, it must be disposed of in accordance with good professional practice, which dictates that drugs considered to be hazardous pharmaceutical waste be disposed of in accordance with applicable state and federal laws and regulations.

As currently written, Subpart 2 implies that nursing homes can return drugs to a pharmacy only if the conditions of the Subpart are met. The Board is proposing to amend Subpart 2 by adding the words "and redispensed" to the first full sentence of the Subpart. Except for controlled substances, nursing homes can return any drug to the dispensing pharmacy so long as the pharmacy accepts responsibility for disposing of any returned drugs in accordance with applicable state and federal laws and regulations concerning the disposal of hazardous pharmaceutical waste. However, in the judgment of the Board returned drugs can be safely redispensed only if the conditions spelled out in the rest of the Subpart are met.

The Board proposes to amend paragraph A of Subpart 2 to require that returned drugs that are redispensed must have been stored in a secure area within the facility. Drugs not stored in a secure area within the facility are subject to tampering by unauthorized personnel, patients or even visitors.

The Board proposes to add a clause that requires that returned drugs that are redispensed must have been returned from a nursing home that has 24 hour per day, seven days per week, on-site licensed nursing coverage. As mentioned above, this ensures that licensed health professionals would either have control of the dispensed

drugs or be able to monitor them 24 hours per day, seven days per week. In the judgment of the Board, not having such licensed nursing coverage increases the risk that drugs will not be stored properly or that they might be tampered with.

The Board also proposes an amendment that clarifies that drugs can be redispensed only if they are returned to the pharmacy that originally dispensed them. In some cases, nursing home orders are sent to a local pharmacy, but the drug is actually dispensed from a different pharmacy owned by the same company. In such cases, the drug should be returned to the dispensing pharmacy for reuse or disposal. The local pharmacy may not have the required records concerning drugs that have been repackaged into unit dose packaging.

When a drug is returned to a pharmacy, it is important that it is not commingled with dosage units of different lot numbers or beyond use dates. Drugs are often recalled by manufacturers by lot number. Commingling drugs with different lot numbers increases the chance that a recalled drug will be dispensed to a patient. Commingling drugs with different beyond use dates increases the chance that expired drugs will be dispensed. The rules currently prohibit commingling of dosage units with different lot numbers. The Board proposes to also prohibit the commingling of dosage units with different beyond use dates.

It is important that patients who may receive returned drugs are notified that the pharmacy accepts and redispenses drugs returned from approved facilities. In the judgment of the Board, drugs returned to pharmacies in accordance with this rule, including the currently proposed amendments, can be safely redispensed. However, patients have the right to make an informed decision as to whether or not they want to accept a drug that has been previously dispensed by the pharmacy.

6800.2810 PRESCRIPTION NUMBERS

Until recently, written prescriptions or oral prescriptions reduced to writing were stored in prescription files. In order for prescriptions to be readily retrievable it was important that they be numbered and filed sequentially. Systems are now available that allow for the scanning and electronic storage of prescriptions. When such a system is used, the sequential filing of paper prescriptions is no longer necessary. Therefore, the Board is proposing to repeal the rule that requires sequential filing of prescriptions.

6800.3000 ACCEPTANCE OF ORDER AND DISTRIBUTION OF MEDICATION; FAX TRANSMISSION OF PRESCRIPTIONS

The electronic transmission of prescriptions from a prescriber's place of practice to pharmacies is becoming more commonplace. The federal Medicare Modernization Act contains a provision that promotes further adoption of electronic prescribing. Gov. Tim Pawlenty's Healthcare Cabinet has also made promotion of electronic prescribing a priority. Finally, Board staff frequently receives questions about electronic prescribing. Therefore, a rule outlining minimal standards for electronic prescribing is necessary.

The Board is proposing that any electronic prescription transmitted from the prescriber to the pharmacy must be in compliance with Minnesota Statutes 325L and conform to the rules of the federal Drug Enforcement Administration (DEA). M.S. 325L is the state's Uniform Electronic Transactions Act. Chapter 325L does not require the use of electronic records, but does set forth detailed standards concerning electronic transactions that do occur. The DEA recently launched a new Controlled Substances Ordering System (CSOS) that DEA registrants can use to order controlled substances from wholesalers. The DEA is working on rules that would also govern the electronic prescribing of controlled substances. Electronic prescribing of controlled substances in this state should conform to any rules that the DEA adopts.

6800.3100 COMPOUNDING AND DISPENSING

The Board is proposing several changes to this rule in order to address changes in pharmacy practice and problems noted by Board staff. Prescription dispensing errors sometimes involve miscommunication when an agent of the prescriber telephones the prescription into the pharmacy. Currently, it is often difficult to determine exactly how such errors occurred because the pharmacist or pharmacist-intern who takes the verbal order does not record the name of the prescriber's agent, nor their own name or initials. Therefore, the Board proposes to require that a verbal order reduced to writing include documentation of the individual communicating the order and the pharmacist or pharmacist intern receiving the order. This requirement would also be useful if the pharmacist or pharmacist-intern wanted to call back to the prescriber's place of practice to verify the validity of a prescription, particularly one for controlled substances.

For similar reasons, the Board proposes that when authorization to refill a prescription is obtained, the name of the practitioner personally authorizing the refill and the name of the practitioner's agent transmitting or communicating the refill authorization, if applicable, be recorded.

The role of pharmacy technicians and their status with the Board have been evolving over the past half dozen years. Pharmacy technicians must now be registered by the Board in order to assist in the performance of certain pharmacy tasks not requiring professional judgment. Personnel working in a pharmacy who are not licensed pharmacists or registered pharmacist-interns or technicians are not allowed to perform pharmacy tasks. Consequently, the Board is proposing to replace the term "supportive personnel" with "pharmacy technicians".

Like the role of technicians, the prescription filling process is also evolving. As mentioned earlier in this statement, systems are now available that allow for the scanning and electronic storage of prescriptions. Once a prescription is scanned into the computer, it can be routed for processing to either a workstation in that pharmacy or to a different pharmacy. If routed to a different pharmacy, the staff there might only enter the order into the computer and conduct a drug utilization review. They might then place the processed prescription in a queue from which the original pharmacy would further

process the prescription by placing the required quantity of drug into a vial, which would be labeled and given to the patient.

This sort of process can allow for greater efficiency because pharmacy staff members can specialize in one part of the filling process. Also, portions of the prescription filling process can be sent from a busy work area or store to one that is less busy. However, because more individuals might be involved in the prescription filling process, there is also an increased risk of errors. Therefore, the Board is proposing to add a Subpart to this rule that requires documentation to identify the name(s), initials, or identification code(s) of each pharmacist, pharmacist intern or pharmacy technician who performed any portion of the prescription filling process. The Board's intention is for each person involved in the prescription filling process to be held accountable for the portion of the work that he or she does.

Patients have the right to make an informed decision about where their prescriptions are filled. Therefore, the Board is proposing to add a Subpart to this rule that would require a pharmacy utilizing services from a central service pharmacy to notify its patients that the pharmacy outsources prescription filling to another pharmacy

6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES.

Patients commonly either want or need to have a prescription transferred between pharmacies. This rule spells out in detail the procedures to be followed when a prescription is transferred. As mentioned earlier in this statement, some pharmacies have started using what are commonly referred to as central fill or central service pharmacies (CSP). A CSP performs tasks such as drug utilization review (DUR) and prescription filling functions such as packaging, labeling, and billing. The CSP passes on information concerning the DUR and/or delivers filled prescriptions to another pharmacy, rather than directly to a patient. The other pharmacy actually dispenses the drug to and counsels the patient.

The transaction between the original pharmacy and the CSP does not constitute a prescription transfer. Therefore, the Board is proposing that a Subpart be added to this rule to clarify that prescription information shared between two pharmacies which are accessing the same real-time, on-line database, pursuant to the operation of a board approved central service operation, is not be considered to be a prescription copy.

6800.3200 PREPACKAGING AND LABELING

As mentioned elsewhere in this statement, the "beyond-use date" is the date after which a drug should not be used. The expiration date printed on a drug package is set by the drug manufacturer. Drugs dispensed in the original packaging retain the manufacturer's expiration date, but when a pharmacist compounds a drug product or repackages commercially available drugs into consumer containers, the manufacturer's expiration date should no longer be used. Instead, the pharmacist is supposed to assign a beyond-use date.

Prepackaging is a form of repackaging. Consequently, this rule needs to be amended to replace the term "expiration date" with the term "beyond-use date". In addition, this proposal changes the method of determining the "beyond-use date" for prepackaged drugs. Please see the discussion in the section below titled, 6800.3350 BEYOND-USE DATES, for further information.

Per Minnesota Rules 6800.3100, Subp. 3, a pharmacist is supposed to check the contents of a prescription medication container and the appearance of the total product. Nevertheless, errors involving the dispensing of an incorrect drug product still regularly occur. Often, the name of the correct drug is printed on the label but a different drug is placed into the prescription container. Therefore the Board is proposing to require that the label of a prepackaged drug contain a physical description of the drug, including any identification code that may appear on tablets and capsules. Systems are available that use the National Drug Code (NDC) of a drug to print a physical description on the label. If the NDC of the correct drug is used to generate a label, but an incorrect drug is placed in the prescription container, a patient or caregiver who compares the description on the label with the drug dispensed would be able to detect the error before taking the drug. This change clearly promotes the safety of patients.

6800.3300 BULK COMPOUNDING

The United States Pharmacopoeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in many other countries outside the United States. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years.

The USP has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). Since the USP is the official public standards setting authority for pharmaceutical products, it is the judgment of the Board that pharmacists should adhere to these standards when compounding. Consequently, this rule change requires pharmacists who compound non-sterile or sterile drug products to adhere to the requirements of USP Chapters 795 and 797, respectively.

6800.3350 EXPIRATION DATES (BEYOND-USE DATES)

As mentioned elsewhere in this statement, the "beyond-use date" is the date after which a drug should not be used. The expiration date printed on a drug package is set by the drug manufacturer. Drugs dispensed in the original packaging retain the manufacturer's expiration date, but when a pharmacist compounds a drug product or repackages commercially available drugs into consumer containers, the manufacturer's expiration date should no longer be used. Instead, the pharmacist is supposed to assign a beyond-use date.

Since this rule concerns drugs that are in some way repackaged by a pharmacy, it needs to be amended to replace the term "expiration date" with the term "beyond-use date". The Subpart concerning bulk-compounded pharmaceuticals is being deleted because USP Chapters 795 and 797, which in the judgment of the Board pharmacists should adhere to when compounding, specify how beyond-use dates should be established.

6800.3400 PRESCRIPTION LABELING

As mentioned above, some pharmacies have started using what are commonly referred to as central fill or central service pharmacies (CSP). A CSP performs tasks such as drug utilization review (DUR) and prescription filling functions such as packaging, labeling, and billing. The CSP passes on information concerning the DUR and/or delivers filled prescriptions to another pharmacy, rather than directly to a patient. The other pharmacy actually dispenses the drug to and counsels the patient.

In the judgment of the Board, central service pharmacies should include on the label of a prescription the name, address, and telephone number of the pharmacy that actually distributes the medication to the patient. The facility that distributes the medication is most likely to be viewed by the patient as his or her pharmacy. In most cases, it will also be closer to the patient's residence than the central-fill pharmacy. Patients should be able to address any questions or concerns they have about their medications to the pharmacy that distributed the medication and that is near their residence.

The label of prescriptions filled, as part of a central service operation, should bear a unique identifier to indicate that the prescription was filled at a central service pharmacy. Such an identifier will allow everyone involved in the prescription filling process, including pharmacy staff and the patient, to know where a prescription was actually filled. Knowing where a prescription is filled is important when trying to resolve problems, such as dispensing errors.

As mentioned above, a pharmacist is supposed to check the contents of a prescription medication container and the appearance of the total product. Nevertheless, errors involving the dispensing of an incorrect drug product still regularly occur. Often, the name of the correct drug is printed on the label but a different drug is placed into the prescription container. Therefore the Board proposes that the label of a prepackaged drug contain a physical description of the drug, including any identification code that may appear on tablets and capsules. Systems are available that use the National Drug Code (NDC) of a drug to print a physical description on the label. If the NDC of the correct drug is used to generate a label, but an incorrect drug is placed in the prescription container, a patient or caregiver who compares the description on the label with the drug dispensed would be able to detect the error before taking the drug. This change clearly promotes the safety of patients.

The Board proposes that, in lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist be allowed, with the consent of the patient, the patient's care giver, or the prescriber, to provide a customized patient medication package (also known as a patient med pak) as defined in the USP Chapter 661 standards. The Board considers such packages to be acceptable medication delivery systems for prescription drugs in certain circumstances. For example, patient med paks are often prepared for patients who have difficulty remembering when to take their medications. All of the doses of medications that are to be taken at a particular time of day are placed in one, labeled container.

The Board currently has no rule concerning the labeling of veterinary prescription drugs. Until recently, most such drugs were dispensed directly by the veterinarian to the owner of the animal or animals for which the drug was prescribed. However, there are now pharmacies specializing in dispensing veterinary drugs to animal owners. Since labeling requirements are different for veterinary prescriptions, the Board is proposing to add a section to this rule that lists the minimum necessary information that must be included, by a pharmacy, on a veterinary prescription label. This new subpart is adapted from the labeling requirements enforced by the Minnesota Board of Veterinary Medicine as found in Minnesota Statutes § 156.18, subd. 2.

6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS

As mentioned earlier in this statement, the "beyond-use date" is the date after which a drug should not be used. The manufacturer sets the expiration date printed on a drug package. Drugs dispensed in the original packaging retain the manufacturer's expiration date, but when a pharmacist compounds a drug product, the manufacturer's expiration date should no longer be used. Instead, the pharmacist should assign a beyond-use date. Many outpatient intravenous admixture drugs are compounded. Consequently, this rule needs to be amended to replace the term "expiration date" with the term "beyond-use date".

The sequential numbering of units of intravenous admixture drugs is an antiquated practice, so the Board proposes to eliminate the portion of this rule that requires it. Having the administration times and/or frequency of administration on the label helps to ensure that patients will receive the drug at the correct time.

Having the pharmacist initial the label of each bag is also an antiquated practice. This portion of the rule dates from the 1970's when the practice helped nurses verify that compounding had actually taken place. Today, pharmacists certify the completion of the order by initialing the compounding record. Therefore, the Board proposes to delete this requirement in order to reflect current pharmacy practice.

6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE

Under Minnesota Statutes § 151.37, subd. 2 and Minnesota Rules 6800.9950 through 6800.9954, prescribers are allowed to perform the dispensing functions that pharmacists normally perform, including the input of prescription order information into electronic data processing equipment. Prescribers are also allowed to delegate data entry to support staff. To help ensure patient safety, it is important for either a pharmacist or the prescriber to verify the accuracy of any information that is entered into an electronic data processing system by support personnel. Therefore, this rule needs to be amended to clarify that a prescriber who takes responsibility for the dispensing of a prescription must verify the accuracy of any information entered into an electronic data processing system by support personnel.

On average, pharmacies fill substantially more prescriptions than they used to fill. Consequently, some pharmacies do not have enough room within the dispensing area to store all of their original prescriptions and other patient-specific records. The Board has granted variances to many pharmacies, allowing them to store such records in secure areas that are outside of the licensed pharmacy. The Board proposes to amend this rule to routinely allow such storage as long as certain conditions are met.

Despite the fact that pharmacists are supposed to verify information entered into an electronic data processing system, errors due to incorrect data entry continue to occur on a fairly regular basis. If such an error occurs when the prescription can be refilled, the error may be repeated with subsequent dispensings. Therefore, the Board previously adopted a rule that requires pharmacists to verify, upon the first refill, that information has been correctly entered by comparing the data entered into the computer with the original hard copy of the prescription. Alternatively, a pharmacy is allowed to develop a quality assurance plan that provides safeguards against errors being made and perpetuated due to inaccurate prescription data being entered into the pharmacy's computer.

Since the adoption of this rule, nearly all pharmacies have chosen to develop a quality assurance plan that includes the comparison of the original hard copy prescription, or an image thereof, to the information entered into the computer. The comparison is usually done up to three days after the prescription is filled. In the judgment of the Board, this sort of quality assurance plan is superior to the alternative of waiting until the first refill to verify the accuracy of the data entry. Waiting until the first refill can mean that the patient is taking a drug incorrectly for days or weeks before the error is caught. Therefore, the Board proposes to amend this rule to require the sort of quality assurance plan that most pharmacies have adopted anyway. The proposed rule sates that the quality assurance check must occur between two to 72 hours after the prescription has been initially certified, unless a different pharmacist does the check. Due to conformational bias, a second check done within two hours, by the same pharmacist, may result in an error going undetected.

Hospitals employ a variety of prescription order entry systems. In addition, nurses

perform a final check of the order before a drug is administered to a patient. In some hospitals, pharmacists round to each nursing unit and check on the accuracy of medication orders. Therefore, the Board proposes that hospital pharmacies be allowed to develop a data entry quality assurance policy that is tailored to the specific data order entry and drug administration systems used in the facility.

6800.4230 SCHEDULE III CONTROLLED SUBSTANCES and 6800.4250 SCHEDULE V CONTROLLED SUBSTANCES

The United States Drug Enforcement Administration (DEA) has proposed the addition of embutramide to the federal controlled substances schedule III. Per the DEA:

> "Embutramide is a derivative of gamma-hydroxybutyric acid (GHB). Its chemical name is N-[2-(m-methoxyphenyl)-2-ethyl-butyl]-gamma-hydroxybutyramide (CAS number 15687-14-6). Embutramide shares pharmacological similarities with other central nervous system (CNS) depressants such as barbiturates, GHB and ketamine. It produces a reversible stupor-like state (narcosis) in experimental animals.
>
> The effects of embutramide on locomotor activity, rearing, forelimb grip strength, hind-limb splay, and the performance of inverted screen tests on rodents were similar to those of pentobarbital. Embutramide produces complete substitution for the pentobarbital discriminative stimulus in mice. Methohexital-trained rhesus monkeys self-administer embutramide.
>
> The pharmacological data suggest that the abuse potential of embutramide may be similar to that of CNS depressants such as barbiturates and their products (Schedules II through IV) and GHB and its product (Schedules I and III) that are controlled under the CSA. Case reports of suicides, attempted suicides, and accidental exposures involving embutramide containing products have been published in the scientific literature".

The DEA has rescheduled buprenorphine to the federal controlled substances schedule III (from schedule V). The DEA found that buprenorphine met the definition of a Schedule III substance in that it has a potential for abuse less than the drugs or other substances in Schedule I or II, but also a currently accepted medical use in treatment in the United States. The DEA found that abuse of buprenorphine may lead to moderate or low physical dependence or high psychological dependence.

The DEA has proposed the addition of pregabalin to the federal controlled substances schedule V. Per the DEA:

> "Pregabalin has been shown to produce effects that are similar to other controlled substances. In a study with recreational users of sedative/hypnotic drugs, a 450 mg dose of pregabalin resulted in subjective ratings of "good drug effect," "high," and "liking" similar to 30 mg of diazepam. In clinical studies, pregabalin showed an adverse event profile similar to other central nervous system depressants. Some of these effects included dizziness, somnolence, ataxia, and confusion. Following abrupt or rapid discontinuation of pregabalin, some patients reported symptoms

suggestive of physical dependence. The FDA determined that the dependence profile of pregabalin, as measured by a patient physical withdrawal checklist, was quantitatively less than benzodiazepines in schedule IV of the CSA".

Per Minnesota Statutes § 152.02, subd. 12, if any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the Board of Pharmacy, the Board shall similarly control the substance. Consequently, the Board is proposing to change these rules so that state scheduling of the aforementioned drugs is consistent with federal scheduling. Doing so will provide consistency within the healthcare community and will enable law enforcement agencies to take appropriate action under state law for possession and sale of controlled substance crimes involving these substances.

6800.4400 REGISTRATION OF CONTROLLED SUBSTANCE RESEARCHERS.

Minnesota Statutes 152.12, subd. 3 requires every person who engages in research involving the use of controlled substances to apply annually for registration by the state Board of Pharmacy. In the judgment of the Board, each such person should have an approved protocol for the use of a controlled substance. In addition, each registrant should have policies and procedures detailing: the precautions that will be taken to prevent theft and diversion of controlled substances, restricting access; procedures for handling wasted drugs; and procedures for handling returns of controlled substances. In order to better account for controlled substances, adequate records must be maintained to show purchase, receipt, use, transfer, and disposal of these drugs. An inventory should be performed at least annually to document control of each stocked controlled substance. In proposing this rule amendment, the Board is taking action to better regulate a group of drugs and other substances that have a significant potential for misuse and abuse.

6800.4500 CONTROLLED SUBSTANCE SAMPLES.

This rule is no longer necessary because the federal Drug Enforcement Administration (DEA) now has a rule regarding the distribution of controlled substance samples that states:

"Complimentary samples of any controlled substance may not be distributed unless the following conditions are met:

1 The distributor has a prior written request from the registrant which includes the customer's name, address, registration number, and name and quantity of the specified controlled substance;

2 The controlled substance is to be used to meet the legitimate medical needs of patients; and

3 Reasonable quantities are requested".

6800.6200 PRESCRIPTION ORDER COMMUNICATION.

It is common for nurses working in licensed facilities such as nursing homes to relay prescription orders to the patient's pharmacy An exact copy of the order that is written in the chart is often mailed or faxed to the pharmacy. However, a nurse sometimes telephones orders into the pharmacy. Confusion over the similarity of drug names accounts for approximately 25% of all reports to the United States Pharmacopoeia - Institute for Safe Medication Practices Medication Error Reporting Program. Sometimes, the confusion is caused by poor handwriting but it is not unusual for miscommunication to occur when a verbal order is relayed to the pharmacy. The National Coordinating Council for Medication Error Reporting & Prevention (NCCMERP) has developed comprehensive recommendations for minimizing medication errors. NCCMERP recommends that the verbal communication of prescriptions or medication orders be limited to urgent situations when immediate written or electronic communication is not feasible. (The NCCMERP is a coalition of 22 organizations, including the National Association of Boards of Pharmacy, the American Medical Association, the American Pharmacists Association and the American Society of Consultant Pharmacists).

In the judgment of the Board, a written prescription signed by the prescriber or a copy of the prescription order as documented in the patient's chart, should either be delivered to the pharmacy or transmitted thereto via facsimile or a secure electronic format. Orders should be telephoned to the pharmacy only when such delivery or transmission is not practical or possible. This rule, as currently written, implies that verbal orders are just as acceptable as written orders or chart documentation. Therefore, this proposed rule change is needed to clarify that written orders or chart documentation are preferred.

6800.7400 HOSPITAL PHARMACIST-IN-CHARGE

The pharmacist-in-charge's span of supervision extends to all areas of the hospital where drugs are stored. Per the current rule, inspections of these areas must take place at least every two months. The purpose of the inspection is to verify: proper drug storage; documentation of distribution and administration of controlled substances; absence of outdated drugs; and the integrity of the required emergency drug supply. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) does not specify the required frequency of such inspections. However, JCAHO Standard MM.2.20 requires that all medication storage areas must be periodically inspected to ensure that medications are properly stored. JCAHO further notes that most organizations conduct these inspections at least monthly. Therefore, this rule needs to be modified to reflect the fact that monthly inspection of all drug storage areas is the standard of practice.

6800.7510 PATIENT CARE

This rule sets forth the requirements for the pharmaceutical service policies that must be developed by the pharmacist-in-charge in a hospital or other institutional pharmacy. This rule needs to be amended to reflect changes in pharmacy practice and in

the regulation of pharmacy.

As now written, the rule requires pharmaceutical service policies to cover the immediate reporting of errors. The current standard of practice is to do more than merely track and report errors. Instead, pharmacies should develop a continuous quality improvement program designed to identify risks to patient safety and to reduce errors by changing policies and procedures in order to eliminate the risks to the extent possible. JCAHO Standard MM.8.10: The hospital evaluates its medication management system, states:

> "The hospital routinely evaluates the literature for new technologies or successful practices that have been demonstrated to enhance safety in other organizations to determine if it can improve its own medication management system."

As mentioned earlier in this statement, the United States Pharmacopoeia has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). Since the USP is the official public standards setting authority for pharmaceutical products, it is the judgment of the Board that pharmacists should adhere to these standards when compounding. Requiring hospital pharmacies to have and adhere to policies regarding both non-sterile and sterile compounding will help ensure that the USP standards are followed, which should help improve patient safety.

6800.7520 ADMINISTRATION (PHARMACEUTICAL SERVICE POLICIES)

This section of the rules addresses more specific hospital pharmaceutical service policies than the previous section. Since this section addresses more than the administration of drugs, the title of the section needs to be changed to "Pharmaceutical Service Policies".

As mentioned above, it is the judgment of the Board that a written prescription signed by the prescriber or a copy of the prescription order as documented in the patient's chart, should either be delivered to the pharmacy or transmitted thereto via facsimile or a secure electronic format. This reduces the incidence of errors due to oral miscommunication or transcription inaccuracies. This proposed rule change is needed to clarify that formats other than facsimile can be used as long as the format produces a direct copy of the order as documented in the patient's chart.

Discrepancies between the information entered by nurses on medication administration records and by pharmacists on pharmacy profiles are one potential cause of confusion and medication errors within hospitals. Consequently, the Board is proposing to require hospitals to establish a pharmacist monitoring system that reconciles a nurse prepared medication administration record (MAR) to the pharmacy profile.

6800.8001 POLICY AND PROCEDURES MANUAL

This section of the rules addresses the policy and procedures manual required of parenteral-enteral home health care pharmacies. Since the Board requires that the manual contain policies and procedures concerning a variety of topics, the phrase "relating to sterile products" needs to be deleted the first sentence of this rule.

As mentioned above, the USP has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). Since the USP is the official public standards setting authority for pharmaceutical products, it is the judgment of the Board that pharmacists should adhere to these standards when compounding. Consequently, this rule change requires parenteral-enteral home health care pharmacies, which compound sterile products, to develop policies and procedures based on USP Chapter 797.

Also mentioned above is the fact that many prescription drugs are considered by either federal or state agencies to be hazardous waste when they are disposed of. Also, many of the chemicals used by pharmacists during the extemporaneous compounding of drug products are toxic, flammable or corrosive. In the judgment of the Board, it is necessary to require that disposal of hazardous pharmaceutical waste be in compliance with Minnesota Hazardous Waste Rules, Chapter 7045. Therefore, this section of the rule needs to be amended to clarify that parenteral-enteral home health care pharmacies need to establish policies for the handling of pharmaceutical and hazardous wastes.

6800.8002 PHYSICAL REQUIREMENTS

This section of the rules addresses the physical requirements that must be met by parenteral-enteral home health care pharmacies. As currently written, this rule lists both space and equipment requirements in detail. However, since it is the judgment of the Board that pharmacists should adhere to USP Chapter 797 when compounding sterile products, a detailed listing of such requirements is no longer needed. Instead, the Board proposes that parenteral-enteral home health care pharmacies be required to adhere to USP Chapter 797 standards for space and equipment.

6800.9700 SERVICE AND FILING OF PAPERS

This section of the rules lists an old address for the Board of Pharmacy offices and needs to be updated to list the new address.

6800.9900 VARIANCES

As currently written, this rule allows anyone subject to the rules of the Board of Pharmacy to request a variance to those rules. The Board sometimes receives variance requests submitted by the headquarters of a large company on behalf of each of the facilities that the company owns. It is clear to the Board that the staff actually working in those facilities is often unaware of the content of the variance requests. In the judgment of the Board, a person responsible for the operation of an individual facility licensed by

the Board should submit variance requests. This helps ensure that facility staff will adhere to any conditions imposed by the Board when it grants a variance request. The conditions imposed by the Board generally help ensure that granting the variance does not adversely affect public safety.

6800.9921 REGISTRATION

This section of the rules addresses the registration of persons or establishments selling or distributing legend medical gases in Minnesota at retail. The proposed rule change is needed to clarify that registered medical gas manufacturers and wholesalers do not need to also register as medical gas retailers.

V. REASONABLENESS OF THE RULES

In developing this package of proposed rule changes, the Board of Pharmacy sought input from a number of different sources. Two ad hoc committees of practicing pharmacists, one focusing on institutional and one on community practice, were convened to advise the Board. The committees each met on several occasions to review and comment on proposed rule changes. The committees included representatives of the Minnesota Pharmacists Association, the Minnesota Society of Health System Pharmacists, chain pharmacy management, long-term care pharmacies, and independent pharmacies. These groups represent virtually all facets of the pharmacy profession that would be affected by these changes.

6800.0100 DEFINITIONS

Beyond-use date and expiration date. The United States Pharmacopoeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in many other countries outside the United States. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years.

Since the Board's proposal is to use the USP beyond-use and expiration date definitions and standards for drugs dispensed to the ultimate consumer, the Board is simply proposing to accept the nationally recognized standard. Certainly this position is a reasonable one.

Central service pharmacy. As mentioned above, some pharmacies have started using what are commonly referred to as central fill or central service pharmacies (CSP). A central service pharmacy usually operates in a manner that is distinct from the types of pharmacies currently licensed by the Board. Therefore, it is necessary and to create a new central service license category. This is reasonable given that the Board is merely amending its rules to reflect the current state of pharmacy practice. Consequently,

"central service pharmacy" needs to be defined in rule.

Community Satellite and Hospital Satellite. While in the past satellite pharmacies were found in the hospital setting, pharmacies have recently opened that operate as satellites of community pharmacies. It is necessary to distinguish between community and hospital satellites since community satellites are not necessarily located within the same facility, as are hospital satellites. This is reasonable because, again, the Board is merely amending its rules to reflect the current state of pharmacy practice.

Long-term care pharmacy. The definition of long-term care pharmacy is being expanded to include pharmacies that provide services to assisted living facilities because such facilities receive essentially the same services from pharmacies that are provided to licensed nursing homes, boarding care homes and supervised living facilities. It is reasonable to expect pharmacies that service assisted-living facilities to follow the rules for providing services to long-term care facilities.

6800.0350 LICENSE CATEGORIES

Refer to the discussion above, in the "needs" section of this statement, that concerns the definition of "central service pharmacies". Also, refer to the preceding section concerning the reasonableness of changes in definitions.

6800.0800 LOCATION, DIMENSION, OR SECURITY CHANGES

Subp. 3 Establishment of a satellite. The Board is receiving requests for approvals of different types of satellite pharmacies. In order to properly evaluate such requests, it is necessary for the Board to review both the plans for the satellite and also the satellite policies and procedures. Since the persons establishing a satellite need to prepare both plans and a set of policies and procedures for the satellite, asking them to supply such documents to the Board will not create an unreasonable burden.

6800.0910 PATIENT ACCESS TO PHARMACIST

As mentioned above, OBRA-90 requires each state to develop laws or rules requiring pharmacists to provide prospective drug-utilization review and patient counseling services to all Medicaid patients. Minnesota did so soon after passage of OBRA-90 and, about a decade later, the Board successfully changed its rules to require prospective DUR and counseling for all patients.

While the Board has noticed some improvement on the part of pharmacists in providing DUR and counseling services to patients receiving new prescriptions, there is definitely room for further improvement. In the judgment of the Board, more patients would be counseled if the pharmacist was required to personally initiate the counseling of a patient for whom a new prescription was being dispensed, rather than having a designee make an offer to counsel. It is reasonable for the Board to take action to increase the

frequency of counseling given that research has shown that drug use review and patient counseling play valuable roles in maximizing the effectiveness of drug therapy, improving patient safety and lowering overall healthcare costs.

In regards to refills, the proposed language requires that a pharmacist must counsel a patient if, based on his or her professional judgment, it is necessary to do so. In order to exercise professional judgment, a pharmacist would need to perform the tasks mentioned in the language that is being proposed for deletion. Consequently, it is reasonable to delete what is, in effect, redundant language.

Some members of the pharmacy community may believe that this proposed rule change will place an additional burden on pharmacists during a time of increasing workloads. However, the rule as amended still allows pharmacists to exercise their professional judgments in determining the extent of counseling given to each patient.

6800.1010 CLOSING A PHARMACY

The DEA requires a pharmacy that closes to notify the DEA of the closure and to return the certificate and order forms. It is reasonable for the DEA to enforce these requirements, since it is the agency that issues the certificate and order forms.

6800.1050 REQUIRED REFERENCES BOOKS AND MINIMUM EQUIPMENT FOR PHARMACIES

Since references books concerning the practice of pharmacy, prescription drugs and toxicology change in terms of their content, format and availability, it is reasonable for the Board to amend its list of suggested references from time-to-time. Since many references are now available in a variety of electronic formats, it is reasonable for the Board to clarify that most references can be available in an electronic format.

The Board receives questions on almost a daily basis concerning controlled substances, indicating that a significant number of pharmacists are not fully aware of the applicable Drug Enforcement Agency regulations (21CFR Part 1300 to end). Therefore, it is reasonable to require each pharmacy to have a current copy of the DEA regulations on hand to minimize the chance that pharmacists will fill prescriptions for controlled substances in violation of federal law.

Since certain specialty pharmacies serve unique populations, it is reasonable to require those pharmacies to have at least one current reference appropriate to the patient population served. This will help ensure that drug therapy for the patients served will be safe and effective.

The United States Pharmacopoeia has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). It is reasonable to expect pharmacies to adhere to these national standards and to follow USP requirements for the type of equipment that must be used. Those pharmacies that seek JCAHO accreditation

will have little choice but to follow USP standards.

In order to ensure that drugs that require refrigeration are stored at the proper temperature, pharmacies need to have a refrigerator with a thermometer. Pharmacies should monitor temperatures in the drug refrigerator on a daily basis to help ensure that drugs that are stored at a temperature outside of the manufacturer's recommend range will not be dispensed to patients. It is reasonable to expect pharmacies to make a very small investment, consisting of a few minutes of time each day and the cost of monitoring logs, in order to safeguard patients.

6800.1250 APPLICATIONS FOR LICENSURE

As mentioned above, the Board no longer requires a practical examination. Instead, the Board requires applicants to pass the NAPLEX, which can be taken at any time. Therefore, this rule change is reasonable because it merely reflects the change in procedure for licensure. In the Board's judgment, this change simplifies the licensing process for applicants while still ensuring the safety of the public.

If an applicant for licensure has not completed all of the steps necessary for licensure within 18 months, it becomes increasingly likely that some change in circumstance will have occurred that would be of concern to the Board. For example, the applicant may have not worked in a pharmacy, in any capacity, for that entire length of time. The Board is charged with protecting the public from, among other things, individuals who are not competent to practice pharmacy. Therefore, it is reasonable to require an applicant who has not completed all of the steps necessary for licensure within 18 months to reapply for licensure so that the Board can determine if the applicant is still qualified to be licensed.

As explained above, the proposed change in this section of the rule concerning fees is merely a technical correction.

6800.1300 RECIPROCITY

As with applicants for licensure by examination, the Board no longer requires applicants for licensure by reciprocity to pass a practical examination. (See discussion about Part 6800.1250 above). Although the practical examination is no longer offered, it is the judgment of the Board that it still necessary for applicants who have not engaged in practice as a licensed pharmacist to demonstrate continued competency. Therefore, the Board is proposing that such applicants be required to take and pass the NAPLEX examination. This is reasonable given that the Board is charged with protecting the public from, among other things, individuals who are not competent to practice pharmacy.

6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE

As mentioned above, this rule change is needed to resolve a conflict with Minnesota Rules 6800.9921. This proposed change is reasonable because, in this case, there is no need for employees of an establishment to register if the establishment itself is registered or has applied for registration. In fact, the Board does not currently register such individuals.

6800.1500 CONTINUING EDUCATION

An organization that accredits continuing education programs and providers has changed its name from the American Council on Pharmaceutical Education to the Accreditation Council for Pharmacy Education. Consequently, part of this proposed rule change is merely a technical correction.

M.S. § 326.56, subd. 2 states, in part, that individuals who are called to active, overseas military duty are exempted from the payment of all renewal fees and from the filing of any application for renewal during the time that the person is the armed forces and for a further period of six months from discharge. This statute specifically mentions renewal fees, penalties for nonpayment of renewal fees and the process of making an application, but not other licensing requirements such as completion of continuing education. However, it is reasonable to assume that the legislature intended that licensing agencies make accommodations for individuals called to active duty.

The Board allows pharmacists to file an application for an extension, not to exceed one year, to comply with the continuing education requirements specified in this rule. Processing, reviewing and following up on such applications require time and effort on the part of Board members and staff. Therefore, it is reasonable to recover the costs associated with processing and following up on these applications by requiring payment of a $100 fee.

6800.2350 PHARMACEUTICAL WASTE

Many prescription drugs are considered by either federal or state agencies to be hazardous waste when they are disposed of. If improperly disposed of, these prescription drugs and chemicals pose a risk to the public. Therefore, in the judgment of the Board it is necessary and reasonable to require that disposal of hazardous pharmaceutical waste be in compliance with Minnesota Hazardous Waste Rules, Chapter 7045. Since the Minnesota Pollution Control Agency already expects pharmacies, wholesalers, manufacturers and other health related facilities to follow the hazardous waste rules, no additional burden is actually being placed on the facilities that the Board licenses.

6800.2600 VENDING MACHINES

The use of automatic medication management systems to distribute prescription drugs can lead to increased efficiencies and reduce certain types of errors, but they can also cause other types of errors. Board of Pharmacy Surveyors, during inspections, have

noted deficiencies in the policies and procedures of some facilities using these systems. Therefore it is reasonable to require the submission of policies and procedures prior to the Board's authorization of the use of an automatic medication management system, so that suggestions can be made that will minimize the chance of errors.

6800.2700 RETURN OF DRUGS AND DEVICES

The Board is proposing amendments to this rule to further ensure that returned drugs are safe to reissue to other patients. An amendment to subpart 1 clarifies that, in a hospital setting, drugs can be returned for reuse or disposal only if they were dispensed for hospital inpatient use and they have not left the span of control of the pharmacy. If this entire rule package is adopted, such areas will have to be inspected at least monthly. It is reasonable to assume that drugs not stored in areas regularly inspected by a pharmacist are more likely to be unsafe for reissue to patients than are drugs stored in areas that are inspected.

In Subpart 1 the phrase "reuse or disposal" emphasizes that, if the drug can't be reused, it must be disposed of in accordance with good professional practice, which dictates that drugs considered to be hazardous pharmaceutical waste be disposed of in accordance with applicable state and federal laws and regulations. (See discussion in pharmaceutical waste section above).

The Board is proposing to amend Subpart 2 by adding the words "and redispensed" to the first full sentence of the Subpart. Except for controlled substances, nursing homes can return any drug to the dispensing pharmacy, so long as:

- the pharmacy agrees to accept the returns;
- the pharmacy accepts responsibility for disposing of any returned drugs in accordance with applicable state and federal laws and regulations concerning the disposal of hazardous pharmaceutical waste.

Adding the words "and redispensed" clarifies that if a pharmacy that accepts returns also wants to redispense them, the remainder of this rule must be followed. The remainder of the rule does not have to be followed if the pharmacy does not redispense the drugs it accepts as returns.

In the judgment of the Board it is reasonable to assume that returned drugs can be safely redispensed only if the conditions spelled out in the rest of the Subpart are met.

- Drugs not stored in a secure area within the facility are subject to tampering by unauthorized personnel, patients or even visitors.

- Requiring that returned drugs that are redispensed must have been returned from a nursing home that has 24 hour per day, seven days per week, on-site licensed nursing coverage ensures that licensed health professionals would either have control of the dispensed drugs or be able to monitor them on a continuous basis.

In the judgment of the Board, not having such licensed nursing coverage increases the risk that drugs will not be stored properly or that they might be tampered with.

- If drugs are returned to a pharmacy that did not originally dispense them, the pharmacy will probably not have the required records concerning drugs that have been repackaged into unit dose packaging.

- For the reasons mentioned above commingling drugs with different lot numbers or beyond use dates increases the chance that a recalled or expired drug will be dispensed to a patient.

It is reasonable to require a pharmacy to notify patients who may receive returned drugs that the pharmacy accepts and redispenses drugs returned from approved facilities. Patients have the right to make an informed decision as to whether or not they want to accept a drug that has been previously dispensed by the pharmacy.

Opponents of this change may argue that if the redispensing of returned drugs is safe, notification of other patients who might receive the returned drugs is not necessary. They may argue that such notification will cause patients to be unduly concerned. However, patients should have the right to decide for themselves whether or not to accept the Board's judgment that returned drugs can be safely redispensed as long as certain conditions are met. Being notified that a pharmacy redispenses returned drugs gives a patient the opportunity to ask questions of the pharmacist about the pharmacy's procedures for handling returned drugs.

6800.2810 PRESCRIPTION NUMBERS

For the reasons mentioned in the "need" section of this statement, the Board is proposing to change this rule to reflect changes in pharmacy practice. Those changes do not adversely affect patient safety, so it is reasonable to adopt this rule change.

6800.3000 ACCEPTANCE OF ORDER AND DISTRIBUTION OF MEDICATION; FAX TRANSMISSION OF PRESCRIPTIONS

The Board is proposing that any electronic prescription transmitted from the prescriber to the pharmacy must be in compliance with Minnesota Statutes 325L and conform to the rules of the federal Drug Enforcement Administration (DEA). It is reasonable to require prescribers and pharmacies to follow a state law, M.S. 325L, which sets forth standards concerning electronic transactions. Since the DEA has authority under federal law to regulate controlled substances it is reasonable to require that the electronic prescribing of controlled substances in this state to conforms to rules that the DEA adopts.

6800.3100 COMPOUNDING AND DISPENSING

The Board proposes to require that a verbal order reduced to writing include documentation of the individual communicating the order and the pharmacist or pharmacist intern receiving the order. The Board also proposes that, when authorization to refill a prescription is obtained, the name of the practitioner personally authorizing the refill and the name of the practitioner's agent transmitting or communicating the refill authorization, if applicable, be recorded. The amount of time needed to comply with these requirements would be very minimal Therefore, these requirements are reasonable in that they would improve patient safety without imposing undue burdens on pharmacists or practitioners.

The Board proposal to replace the term "supportive personnel" with "pharmacy technicians" is reasonable in that it reflects the evolving roles of technicians and other support staff.

For the reasons mentioned in the "needs" section of this statement, the Board is proposing to add a Subpart to this rule that requires documentation to identify the name(s), initials, or identification code(s) of each pharmacist, pharmacist intern or pharmacy technician who performs any portion of the prescription filling process. This is reasonable in that each person involved in the prescription filling process is held accountable for the portion of the work that he or she does but the required documentation should not significantly increase the amount of time and effort required to fill prescriptions.

The Board is proposing to add a Subpart to this rule that would require a pharmacy utilizing services from a central service pharmacy to notify its patients that the pharmacy outsources prescription filling to another pharmacy. This is reasonable because it would require very little effort and patients have a right to know where their prescriptions are being processed.

6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES.

As mentioned above, the Board is proposing that a Subpart be added to this rule to clarify that prescription information shared between two pharmacies which are accessing the same real-time, on-line database, pursuant to the operation of a board approved central service operation, is not considered to be a prescription copy. This proposal is reasonable in that it reflects changes in pharmacy practice and yet patient safety will not be adversely affected.

6800.3200 PREPACKAGING AND LABELING

Prepackaging is a form of repackaging. Consequently, this rule needs to be amended to replace the term "expiration date" with the term "beyond-use date". In addition, this proposal changes the method of determining the "beyond-use date" for prepackaged drugs. Since the Board's proposal is to use the USP beyond-use and

expiration date definitions and standards for drugs dispensed to the ultimate consumer, the Board is simply and reasonably proposing to accept the nationally recognized standard.

The Board is proposing to require that the label of a prepackaged drug contain a physical description of the drug, including any identification code that may appear on tablets and capsules. Systems are available that use the National Drug Code (NDC) of a drug to print a physical description on the label. If the NDC of the correct drug is used to generate a label, but an incorrect drug is placed in the prescription packaging, a patient or caregiver who compares the description on the label with the drug dispensed would be able to detect the error before taking the drug. This change may require pharmacies to incur system costs but it clearly promotes the safety of patients and therefore, in the Board's judgment, it is reasonable.

6800.3300 BULK COMPOUNDING

The USP has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). Since the USP is the official public standards setting authority for pharmaceutical products, it is reasonable for the Board to require that pharmacists adhere to these standards when compounding.

6800.3350 EXPIRATION DATES (BEYOND-USE DATES)

This rule concerns drugs that are in some way repackaged by a pharmacy, so it needs to be amended to replace the term "expiration date" with the term "beyond-use date". The Subpart concerning bulk-compounded pharmaceuticals is being deleted because USP Chapters 795 and 797 specify how beyond-use dates should be established. Since the Board's proposal is to use the USP beyond-use and expiration date definitions and standards for drugs dispensed to the ultimate consumer, the Board is simply and reasonably proposing to accept the nationally recognized standard.

6800.3400 PRESCRIPTION LABELING

Please refer to the portion of the needs section that addresses central service pharmacies for a description of how those pharmacies operate. In the judgment of the Board, central service pharmacies should include on the label of a prescription the name, address, and telephone number of the pharmacy that actually distributes the medication to the patient. This is reasonable because patients should be able to address any questions or concerns they have about their medications to the pharmacy that distributed the medication and that is probably closest to their residence.

The label of prescriptions filled, as part of a central service operation, should bear a unique identifier to indicate that the prescription was filled at a central service pharmacy. This is reasonable because knowing where a prescription is filled is important when trying to resolve problems, such as dispensing errors. Also, patients have a right to know where their prescriptions have been filled.

The Board proposal to require the label of a prepackaged drug to contain a physical description of the drug, including any identification code that may appear on tablets and capsules is reasonable because it promotes patient safety as described in the needs section In addition, pharmacy software that allows for printing of such information on a label is available. Existing pharmacy software can probably also be modified so this requirement can be met.

The provision of customized patient medication packages (also known as a patient med paks) are defined in the United States Pharmacopoeia (USP) Chapter 661 standards. Since the USP is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States, it is reasonable to allow the dispensing of medications in med paks. .

Since there are now pharmacies specializing in dispensing veterinary drugs to animal owners, it is reasonable to establish labeling requirements for such drugs. This new subpart is adapted from the labeling requirements enforced by the Minnesota Board of Veterinary Medicine as found in Minnesota Statutes § 156.18, subd. 2.

6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS

See above for an explanation of the difference between expiration dates and beyond-use dates. Many outpatient intravenous admixture drugs are compounded. Consequently, it is reasonable to amend this rule needs to replace the term "expiration date", which is something that a manufacturer establishes, with the term "beyond-use date", which is something a pharmacist assigns to a compounded product. The Board is reasonably proposing to accept the nationally recognized standard.

It is reasonable to eliminate the rule that requires the sequential numbering of units of intravenous admixture drugs because the procedure is antiquated. Having the administration times and/or frequency of administration on the label helps to ensure that patients will receive the drug at the correct time and is thus reasonable.

It is reasonable to eliminate the rule that requires the pharmacist to initial the label of each bag because that is also an antiquated practice.

6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE

Prescribers who dispense prescriptions are allowed to delegate data entry to support staff. To help ensure patient safety, it is important for the prescriber to verify the accuracy of any information that is entered into an electronic data processing system by support personnel. Pharmacists currently verify data entry done by support staff and it is thus reasonable to require dispensing prescribers to do the same.

The Board has already granted variances to many pharmacies, allowing them to

store records in secure areas that are outside of the licensed pharmacy. To date, the Board has heard of no problems with offsite, secure storage. Therefore, the Board's proposal to amend this rule to routinely allow such storage, as long as certain conditions are met, is reasonable.

As mentioned above, the Board previously adopted a rule that requires pharmacists to verify, upon the first refill, that information has been correctly entered by comparing the data entered into the computer with the original hard copy of the prescription. Alternatively, a pharmacy is allowed to develop a quality assurance plan that provides safeguards against errors being made and perpetuated due to inaccurate prescription data being entered into the pharmacy's computer. Since the adoption of this rule, nearly all community pharmacies have chosen to develop a quality assurance plan that includes the comparison of the original hard copy prescription, or an image thereof, to the information entered into the computer. In the judgment of the Board, this sort of quality assurance plan is superior to the alternative of waiting until the first refill to verify the accuracy of the data entry. Since most community pharmacies are already using the sort of quality assurance procedures that the Board is proposing, this suggested rule change is reasonable.

Hospitals employ a variety of prescription order entry systems. In addition, nurses perform a final check of the order before a drug is administered to a patient. Since an additional licensed health professional checks the drug prior to administration to the patient, it is reasonable to allow hospital pharmacies to develop a data entry quality assurance policy that is tailored to the specific data order entry and drug administration systems used in the facility.

6800.4230 SCHEDULE III CONTROLLED SUBSTANCES and 6800.4250 SCHEDULE V CONTROLLED SUBSTANCES

The Board's proposals for scheduling or rescheduling various controlled substances in Schedules III-V are designed to be compatible with the scheduling done by the Drug Enforcement Administration Act at the federal level. Since pharmacists are already obliged to meet the federal requirements regarding the handling of the various controlled substance drugs, no new activities are being required of Minnesota pharmacists through the adoption of this rule. Including the various items being proposed for addition to the state's list of controlled substance drugs, however, gives law enforcement agencies and professional licensing boards opportunities to take action under state law, rather than having to develop federal cases for violations of the various controlled substance statutes.

Since the Board's proposal for the scheduling of these various substances follows state and federal law, the Board's proposal is a reasonable one.

6800.4400 REGISTRATION OF CONTROLLED SUBSTANCE RESEARCHERS.

Given that controlled substances have a significant potential for misuse and abuse, controlled substance researchers should be subject to reasonable rules. Academic researchers and law enforcement personnel who need access to controlled substances should already have approved protocols for the use of controlled substances. Each registrant should already have policies and procedures detailing: the precautions that will be taken to prevent theft and diversion of controlled substances, restricting access; procedures for handling wasted drugs; and procedures for handling returns of controlled substances. In order to better account for controlled substances, researchers should already be maintaining adequate records and performing regular inventories. Therefore, it is reasonable for the Board to require in rule those activities that most researchers already perform.

6800.4500 CONTROLLED SUBSTANCE SAMPLES.

It is reasonable to delete this rule because the federal Drug Enforcement Administration (DEA) now has a rule regarding the distribution of controlled substance sample, as described in the "Needs" section above.

6800.6200 PRESCRIPTION ORDER COMMUNICATION.

As mentioned above, the National Coordinating Council for Medication Error Reporting & Prevention (NCCMERP) has developed comprehensive recommendations for minimizing medication errors. NCCMERP recommends that the verbal communication of prescriptions or medication orders be limited to urgent situations when immediate written or electronic communication is not feasible. Therefore, in order to minimize medication errors, it is reasonable to require that a written prescription signed by the prescriber or a copy of the prescription order as documented in the patient's chart, should either be delivered to the pharmacy or transmitted thereto via facsimile or a secure electronic format. (And that orders should be telephoned to the pharmacy only when such delivery or transmission is not practical or possible).

6800.7400 HOSPITAL PHARMACIST-IN-CHARGE

As mentioned above, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standard MM.2.20 requires that all medication storage areas must be periodically inspected to ensure that medications are properly stored. JCAHO further notes that most organizations conduct these inspections at least monthly. Therefore, it is reasonable for this rule to be modified given that monthly inspection of all drug storage areas is the standard of practice.

6800.7510 PATIENT CARE

As mentioned above, the current standard of practice is to do more than merely track and report errors. JCAHO Standard MM.8.10 requires hospitals to evaluate their medication management systems on a routine and ongoing basis. It is reasonable to amend this rule to reflect the current standard of practice.

As mentioned earlier in this statement, the United States Pharmacopoeia has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). Since the USP is the official public standards setting authority for pharmaceutical products, it is the judgment of the Board that pharmacists should adhere to these standards when compounding. Requiring hospital pharmacies to have and adhere to policies regarding both non-sterile and sterile compounding will help ensure that the USP standards are followed, which should help improve patient safety. Again, it is reasonable to adopt, in rule, national standards of practice.

6800.7520 ADMINISTRATION (PHARMACEUTICAL SERVICE POLICIES)

This section of the rules addresses more specific hospital pharmaceutical service policies than the previous section. Since this section addresses more than the administration of drugs, the title of the section needs to be changed to "Pharmaceutical Service Policies".

See 6800.6200 Prescription Order Communication (above in this section) for an explanation of the reasonableness for changing the rule regarding the communication of prescription orders to the pharmacy.

As mentioned above, discrepancies between the information entered by nurses on medication administration records and by pharmacists on pharmacy profiles are one potential cause of confusion and medication errors within hospitals. The Board's proposal to require hospitals to establish a pharmacist monitoring system that reconciles a nurse prepared medication administration record (MAR) to the pharmacy profile is reasonable because it should improve patient safety, while not being overly burdensome to the pharmacy. This sort of reconciliation is also required by JCAHO as part of a larger medication reconciliation process.

6800.8001 POLICY AND PROCEDURES MANUAL

This section of the rules addresses the policy and procedures manual required of parenteral-enteral home health care pharmacies. Since the Board requires that the manual contain policies and procedures concerning a variety of topics, in addition to sterile products, the phrase "relating to sterile products" needs to be deleted the first sentence of this rule.

As mentioned earlier in this statement, the United States Pharmacopoeia has established updated standards for non-sterile and sterile compounding. (USP Chapters

795 and 797). Since the USP is the official public standards setting authority for pharmaceutical products, it is the judgment of the Board that pharmacists should adhere to these standards when compounding. Requiring parenteral-enteral pharmacies to have and adhere to policies regarding both non-sterile and sterile compounding will help ensure that the USP standards are followed, which should help improve patient safety. Again, it is reasonable to adopt in rule national standards of practice.

Many prescription drugs are considered by either federal or state agencies to be hazardous waste when they are disposed of. If improperly disposed of, these prescription drugs and chemicals pose a risk to the public. Therefore, in the judgment of the Board it is necessary and reasonable to require that disposal of hazardous pharmaceutical waste be in compliance with Minnesota Hazardous Waste Rules, Chapter 7045. Since the Minnesota Pollution Control Agency already expects pharmacies, wholesalers, manufacturers and other health related facilities to follow the hazardous waste rules, no additional burden is actually being placed on the facilities that the Board licenses.

6800.8002 PHYSICAL REQUIREMENTS

As mentioned in several other sections the Board finds that it is reasonable for pharmacists to adhere to the national USP Chapter 797 standards for sterile compounding.

6800.9700 SERVICE AND FILING OF PAPERS

This section of the rules lists an old address for the Board of Pharmacy offices and needs to be updated to list the new address and is therefore merely a technical change.

6800.9900 VARIANCES

Nothing in this rule would prevent a large chain from developing a standard variance request for use by all of its stores. However, the Board finds that it is reasonable for the person responsible for the operation of an individual facility licensed by the Board to review, sign and submit variance requests. This helps ensure that facility staff will adhere to any conditions imposed by the Board when it grants a variance request. It also helps ensure that facility staff will actually be aware of the contents of a variance request.

6800.9921 REGISTRATION

This section of the rules addresses the registration of persons or establishments selling or distributing legend medical gases in Minnesota at retail. The proposed rule change is needed to clarify that registered medical gas manufacturers and wholesalers do not need to also register as medical gas retailers. As a clarification, this is really just a technical change.

VI. REGULATORY ANALYSIS

Minnesota Statutes § 14.131 sets out several factors that must be considered in the Statement of Need and Reasonableness. Each factor will be listed separately and will be followed by the Board's response.

1. "a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;"

The persons most directly affected by the proposed rule changes are Minnesota pharmacists, pharmacy owners, pharmacy technicians, pharmacist interns and support staff. Pharmacy owners would bear most of the costs associated with the rule changes. The other persons listed might experience changes in the policies and procedures used in their work settings. Some of the proposed rule changes might slightly increase workloads but others will probably result in increased efficiencies.

Practitioners who can prescribe, and their agents, might be affected by some of the rules involving the transmission of prescription information.

Finally, the public will be affected by, and will benefit from, many of these proposed rule changes because the changes should result in the safer provision of pharmacy services. They will most directly benefit from increased patient counseling and drug use review and better prescription labeling.

2. "the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule, and any anticipated effect on state revenues;"

The only cost that the Board of Pharmacy might incur is a small one related to system changes needed to establish a new category of pharmacy licensure. None of the other proposals are likely to result in any costs to the Board or significant costs to other state agencies. It is possible that the pharmacies operated by state agencies such as the Minnesota Department of Human Services might have relatively minor costs related to upgrading computers and other equipment. There is no anticipated effect on state revenues.

3. "a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;"

Many of these proposed rule changes simply reflect evolving standards for pharmacy practice. As noted in many sections, new standards have been developed by the United States Pharmacopoeia and the Joint Commission on Accreditation of Healthcare Organizations. In addition, the National Coordinating Council for Medication Error Reporting & Prevention, the Drug Enforcement Administration and the Minnesota

Pollution Control Agency all have rules or standards concerning various aspects of pharmacy practice. There may be "less costly and intrusive" methods of dealing with compounding, disposal of hazardous pharmaceutical waste, communication of prescription orders, medication reconciliation, continuous quality improvement and other issues. However, those less costly and intrusive measures would not be in compliance with the standards set by the above-mentioned state and national organizations. They would also not adequately achieve the purpose of these proposed rules, which is to further improve the health, safety and welfare of the public.

In addition, adoption of these newer standards may decrease medication errors and drug-related morbidity and mortality. That, in turn, would decrease costs for patients, insurers, employers, federal, state and local governments and society as a whole.

Some of the proposed changes, by their nature, will mean that licensees of the Board will be less regulated or will in some way benefit from the changes. Licensees called to active military duty will have continuing education requirements waived. Individuals closing a pharmacy will have less to report to the Board. Antiquated rules that require the sequential numbering of units of intravenous admixture drugs and initialing of each bag's label are being changed. The list of acceptable reference books is being updated. Prescription information shared between two pharmacies which are accessing the same real-time, on-line database, pursuant to the operation of a board approved central service operation, will not have to be treated as a prescription copy.

The quality assurance procedures that would be required under part 6800.3950 are already used by the vast majority of pharmacies in Minnesota.

4. "a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;"

As noted elsewhere in this document, the Board employed a very open process when developing this package of proposed rule changes. The Board used two committees to assist it in the development of these proposed changes. The committees had members drawn from many areas of the pharmacy profession in Minnesota, including representatives of the two major professional associations of pharmacists in Minnesota.

The Board considered alternative methods for achieving the purposes of the proposed rule changes throughout the rule-making process. The final draft of the proposed rules already incorporates many of the alternatives proposed by members of the advisory committees or by individuals giving testimony at the Board meeting at which the Board formally adopted the language of this rules package.

5. "the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals;"

There may be costs, born by pharmacies and other healthcare facilities, to comply with the proposed rule changes in the areas listed below. However, many of these changes have been recommended or mandated by the USP, the DEA, JCAHO, the Minnesota Pollution Control Agency or other governmental or standard setting organizations. Therefore, pharmacies would have many of these costs even if the Board did not change its rules. The rule changes most likely to result in costs are as follows:

- Those rules concerning non-sterile and sterile compounding facilities, equipments and procedures. In order to comply with USP Chapters 795 and 797 requirements, it is likely that pharmacies will need to invest in additional equipment and, in the case of sterile compounding, may have to remodel their facilities. Many pharmacies have already voluntarily made these changes.
- Those rules concerning the disposal of pharmaceutical waste. Pharmacies may need to contract with a company licensed to accept and dispose of pharmaceutical waste. However, the Minnesota Pollution Control Agency has recently been levying fines against some pharmacies that have not been following laws and rules regarding the disposal of pharmaceutical waste.
- Those rules that would require that the label of prescription containers and prepackaged drugs contain a physical description of the drug, including any identification code that may appear on tablets and capsules. Pharmacies that do not already use software that allows for the inclusion of this information on labels may need to invest in software that does. Alternatively, they may have to have their current software vendor update their existing program.
- The proposed fee that would be assessed in order to cover the costs of handling requests for an extension of time to complete the required continuing education requirement. The $100 fee will be an expense for pharmacists who feel it necessary to file for such extensions.
- Monitoring temperatures of refrigerators in which drugs are stored. There will probably be a relatively small cost for the purchase of the monitoring logs or equipment necessary to comply with this rule change.

6. "the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals"

In the judgment of the Board, many of these proposed rule changes will promote the safer use of medications. They will reduce medication errors and drug-related morbidity and mortality. If these rules are not adopted, patients will be more likely to experience these problems. That will result in increased costs to patients, insurers, employers, federal, state and local governments and society in general. Pharmacies may also have increased costs due to more costly malpractice insurance premiums and to legal judgments rendered against them.

7. "an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference."

There are federal laws, rules and standards that address the patient counseling and DUR provisions of OBRA 90, the listing of controlled substance drugs, the handling of pharmaceutical waste, and sterile and non-sterile compounding. In the case of patient counseling and DUR, the Board's proposed rule change should actually encourage greater compliance with federal law.

In the case of the Board's scheduling of the aforementioned controlled substance drugs, the handling of pharmaceutical waste and sterile and non-sterile compounding, the Board's proposals brings state rules into conformity with federal laws, rules and standards.

8. a description of "how the agency, in developing the rules, considered and implemented the legislative policy supporting performance-based regulatory systems set forth in section 14.002".

In developing these rules, the Board has allowed flexibility in meeting the requirements in a number of different areas. In the area of providing patient counseling and DUR services to patients, the Board has not attempted to limit pharmacists in the manner in which such services are provided. Pharmacists have flexibility in using their best professional judgment regarding the provision of counseling services to patients and may utilize their own intrinsic knowledge or rely on any number of computer software programs designed to provide prospective drug use review. Similarly, pharmacists may chose from a variety of vendors when modifying or purchasing software in order to comply with the proposed changes in labeling.

There are also a number of different ways for pharmacies to come into compliance with USP 795 and 797 compounding standards. The Board already makes recommendations to pharmacies to help them select the most appropriate and cost-effective solutions for meeting these standards.

Many of the proposed rule changes would require licensees to follow certain rules, laws and standards that are administered by other federal and state agencies and that they should already be following. Those proposed changes are meant to clearly indicate, in the chapter of rules that licensees are most likely to review, that the existing rules, laws and standards of the other agencies need to be followed. Thus, the regulatory burden of licensees is not being increased by these rules.

Other proposed rule changes actually reduce the regulatory burden for licensees. For example, pharmacists who are called to active military duty will not be required to complete continuing education for the duration of time that they are on such duty. Also, pharmacists will have more discretion when determining the extent to which patients should be counseled when they are picking up refill prescriptions.

VII. Additional Notice

Minnesota Statutes, Sections 14.131 and 14.23, require the Board to describe the efforts made to provide additional notification to persons or classes affected by the proposed rule or explain why such efforts were not made.

The Board proposes the following steps to provide notice to any affected parties:

1. The Board has published a request for comments in the State Register and has mailed a copy of it to all persons on the Board's rulemaking list.

2. The Board will publish the official notice of intent in the State Register and will mail copies of it to all persons on the Board's rulemaking list. The Board will also mail a copy of the proposed rules to all such persons.

3. The Board will post a notice of its intent to engage in the rulemaking process, the statement of need and reasonableness, and the proposed rules on the Board's website. A notice of the website posting of the aforementioned documents will be sent, via e-mail, to every pharmacist, pharmacist intern, and pharmacy technician for whom the Board has an e-mail address.

4. The Board will make copies of the aforementioned documents available in alternative formats, as requested.

VIII. List of Witnesses

If the rules go to a public hearing, the Board anticipates having the following witness testify in support of the need and reasonableness of the rule:

Cody Wiberg, Pharm.D., R.Ph.
Executive Director
Minnesota Board of Pharmacy

This individual would testify regarding all aspects of the Board's proposal.

IX. Contact with Legislative Sponsors About the Proposed Rule

According to Minnesota Statutes § 14.116, if the mailing of a Notice of Intent to Adopt Rules is within two years of the effective date of the law granting the agency authority to adopt the proposed rules, an agency must make reasonable efforts to send a copy of the Notice and the Statement of Need and Reasonableness to all sitting legislators who were chief house and senate authors of the bill granting the rulemaking authority. Since the law granting the Board of Pharmacy the authority to develop rules to regulate pharmacy practice appears to have been passed in 1937, the requirement to notify the chief authors expired long ago.

Minnesota Statutes § 14.116 also requires an agency to send a copy of the Notice and the Statement of Need and Reasonableness to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules. Therefore, a copy of the Notice of Intent to Adopt Rules and a copy of the Statement of Need and Reasonableness will be sent to: Senators Becky Lourey and Michelle Fischbach, Chair and Ranking Minority Member, respectively, of the Health and Family Security Committee; Senators Linda Berglin and Brian LeClair, Chair and Ranking Minority Member, respectively, of the Health, Human Services and Corrections Budget Division; Senators Leo T. Foley and Carrie L. Ruud, Chair and Ranking Minority Member, respectively, of the Crime Prevention and Public Safety Committee; Senators Jane B. Ranum and Thomas M. Neuville, Chair and Ranking Minority Member, respectively, of the Public Safety Budget Division; Representatives Fran Bradley, Thomas Huntley and Mary Ellen Otremba, Chair and Minority Finance and Policy Leads, respectively, of the Health Policy and Finance Committee; and Representatives Steve Smith, Mary Murphy and Michael Paymar, Chair and Minority Finance and Policy Leads, respectively, of the Public Safety Policy and Finance Committee. A certificate of mailing will be done to acknowledge the mailings and will be included with the documents submitted to the Office of Administrative Hearings as part of the rulemaking record.

X. Summation

This rules package is being proposed in order to make changes that are necessary, in the Board's judgment, to better protect the health and welfare of the public. The Board has worked hard to develop proposed rule changes that should also be acceptable to the majority of the members of the profession. Board staff conducted background research to assess the current state-of-the-art for pharmacy practice and to identify rules in need of updating. The Board also used two ad hoc committees to assist it in the development of this rules package. These committees, each of which met several times, included individuals representing many areas of the pharmacy profession in Minnesota. Included on the committees were representatives of the two major professional associations of pharmacists in Minnesota. In addition, the Board heard public comments concerning these proposed rule changes at its November 15, 2005 meeting.

Through the information contained in this Statement of Need and Reasonableness, the Board has demonstrated that it has fulfilled its responsibility of protecting the public health in Minnesota, as it relates to pharmacy services; while, at the same time, providing flexibility to pharmacists in the manner in which they choose to practice.

Cody Wiberg

Cody Wiberg, Executive Director
Minnesota Board of Pharmacy

9/7/06

Date